Introduction

Patients with thoracic aortic disease, often reflecting life-threatening conditions, are a difficult population to treat, as they frequently consist of an aged population with multiple comorbidities. The modern surgical treatment of thoracic aortic disease began in the 1950s when successful treatment using segmental resection and graft replacement was reported by DeBakey (1). Conversely, endovascular management has emerged during the last decade as a valuable treatment modality for simple and complex disorders involving both the distal arch and descending thoracic aorta (2, 3) (Fig. 1). Frequently encountered problems associated with an open repair, such as thoracotomy, aortic cross-clamping, left-heart bypass, and single-lung ventilation, can be avoided by endovascular procedures. Additionally, patients subjected to endovascular thoracic procedures enjoy a significantly shorter hospitalization compared to those who underwent open repair. As experience grows, the range of endovascular cases in major centres is becoming increasingly challenging, and calls not only for complex hybrid approaches to arch and thoraco-abdominal aneurysms, but also for management of ruptured aorta and lesions with unfavourable anatomy (4). Nonetheless, the challenge of providing conformability and fixation in the aortic arch and thoracic aorta is substantial, given the 3-dimensional spiralling of the thoracic aorta with each ventricular contraction (Fig. 2). Meanwhile, only the capacity of thoracic stent-graft to appose tightly to the aortic wall ensures effective sealing and fixation, avoids endoleak and migration, and ultimately successful endovascular repair with aortic remodeling. Conformability is therefore the combined effect of mimicking thoracic aortic anatomy and good aortic wall apposition. This review is an overview of various commercially available stent-graft types with focus...
on associated procedure-related and device-related problems and device conformability.

**Stent-graft type and technical development**

After first successful implantation of endovascular stent-graft in patients with abdominal aortic aneurysm by PARODI et al. with good short- and mid-term results (5), DAKE et al. applied the technique for treatment of thoracic aortic aneurysms. First-generation stent-grafts were manufactured using 2.5-cm self-expanding Gianturco Z stents (Cook Co., Bloomington, Indiana), knitted and covered with woven Dacron (Meadow-Boston Scientific, Natick, Massachusetts). These stent-grafts were oversized 10 to 15% to the cross-sectional diameter of the aorta as measured by computed tomography (CT) in an effort for sufficient radial force to achieve endosealing and prevent stent-graft migration (6). Complete aneurysm thrombosis was achieved in 83% of patients at an early mortality rate of 9%. Treatment failure occurred in 38 of the 103 patients, with five patients requiring open surgery for endoleaks associated with aneurysm enlargement. Overall actuarial survival rate was 82%, 49%, and 27% at 1, 5, and 8 years, respectively (7). This feasibility trial with the first-generation or so called “home-made” stent-grafts demonstrated that endovascular stent-graft repair was an option in high-risk patients. Major challenges associated with endovascular procedures with the first generation endografts ranged from a relative rigidity and considerable size of the delivery system, to the failure of thoracic endografts to conform tightly to the anatomy of the aorta. As a consequence, lack of conformability was recognized as the reason for graft instability, endoleak and procedural failure. With recent use of endovascular stent-grafts for treatment of type B aortic dissection (8) the technique has generated even more interest for acute scenarios. Among available endoprotheses, the Gore TAG (WL Gore & Associates, Flagstaff, Arizona) is composed of a symmetrical expanded polytetrafluoroethylene (ePTFE) tube externally reinforced with a layer of ePTFE or fluorinated ethylene propylene (FEP) (Fig. 3). An exoskeleton consisting of nitinol stents is attached to the entire external surface of the graft with ePTFE/FEP bonding tape. Both proximal and distal segments of the endograft have scalloped flares to facilitate endograft conformability in a tortuous thoracic aorta. Two radio-opaque gold bands are attached to the base of the flares serving as a guide during deployment. Following the device deployment, a unique trilobed balloon, which permits continuous
antegrade aortic blood flow during balloon inflation, is
used to ensure full device attachment to the aortic wall.
Similarly, the Zenith TX2 endograft is constructed of
Dacron fabric covered by stainless steel Z-stents. The
proximal end is covered and has stainless steel barbs pro-
truding through the graft fabric and anchoring the graft
directly to the aortic wall. The distal bare stent compo-
nent is constructed of stacked Z-stents joined by
polypropylene sutures, which can be deployed through a
16-French sheath and inserted through the existing
Zenith TX2 proximal component sheath. The Z-stent
exert minimal radial force, allowing gradual apposition
of the dissection septum and reexpand the true lumen.
The large open strut architecture allows maintenance of
branch vessel perfusion, so that the stent can be safely
deployed across the origins of intercostals, visceral, and
renal arteries. The Talent thoracic stent-graft system
(Medtronic, Santa Rosa, California) is composed of a
nitinol stent between layers of polyester graft. It has a
longitudinal support bar throughout the length of the
endo graft, which provides column strength while main-
taining device flexibility to accommodate tortuous ves-
sels. In an effort to improve deployment accuracy and
technical ease, the long connecting bar of the Talent
device has been removed in second generation Valiant
device, in which columnar support has been optimized
by stent spacing and exoskeleton. The removal of longi-
tudinal connecting bar enables better flexibility. The
second-generation Valiant stent-graft has a modified
proximal configuration with 8-bare peak wires instead of
5-bare peak wires of the Talent stent-graft. This modifi-
cation with less stent flar distributes similar radial force
across more points of contact with less force and stress
per point of contact. SUZUKI et al. compared the
Gianturco Z-stent graft and Spiral Z-stent graft in 45
patients with a mean follow-up of 10.5 months. The inci-
dence of dissection and ulcer like projections after 10.5
months was significantly higher in patients with
Gianturco Z-stent (38%) than those with Spiral Z-stents
(8%) (p < 0.05). This lower incidence may be attributed
to the fact that Spiral Z-stents are more flexible and con-
formable with the arch curvature than are Gianturco Z-
stents. Gianturco Z-stents are somewhat inflexible and
return to their original straight structure when deployed
in the arch of the descending thoracic aorta. Stent inflex-
ibility may increase the radial force of the distal end of
the stent graft against the aortic wall and induce injury to
the aortic intima, leading to new ulcer-like projections
and recurrent dissection at the site of local trauma (9). In
addition, mechanical failure of stent-graft materials con-
tinues to be a potential problem. The inherent properties
of the resistance of metal and graft combined with extrin-
sic forces contribute significantly to the risk of device
fatigue. Once implanted, the device is subject to extrin-
sic forces imposed by individual geometry of the tortu-
ous aorta and the impact of continuous high blood pres-
sure. Mechanical failure of the stent-graft can occur as a
result of metallic fracture, fabric wear, and suture break-
age (Fig. 4). Recent large series identified 60 patients
(9%) with mechanical failure of the stent-graft out of 618
patients who underwent aortic stent-graft placement with
43 cases (6.9%) of metallic stent fracture, 14 suture dis-
ruptions (2.3%), and three cases of graft wear (0.5%).
The average time to the recognition of any mechanical
failure of an prosthesis was 19 months. Surgical conver-
sion was required in six cases, while the others (n = 54)
remained asymptomatic and did not undergo any inter-
vention (10).

Fig. 4
(Left) Rupture of an thoracic aortic stent-graft after previous bulging nine month after implantation. (Right) Follow-up CT-scan after placement of a further stent-graft.
Proximal fixation in the aortic arch

Navigating the aortic arch branches ranks among the most significant unresolved and controversial issues (2, 11). Endovascular treatment of aortic arch pathology often involves a proximal landing zone in the angulated aortic arch (12). Successful endovascular repair, however, requires effective sealing and fixation to avoid stent-graft migration, collapse, or proximal type I endoleaks. Several factors may influence the results of stent-graft repair, including the nature of the proximal aortic landing zone (length, angulation, and morphology of the aortic wall), and the choice of device. Recent experimental work with a benchtop pulsatile flow model tested both the anchorage of four commercially available stent-grafts (TAG, Zenith TX, Valiant and Relay) in the proximal landing zone at varying angles (70° to 140°) and the effect of oversizing (5% to 37%) in 15 human thoracic cadaveric aortas (13). The lack of device-to-wall apposition was measured as a function of landing zone angulation and oversizing during static and dynamic testing (60 pulses/min, 300/150 mmHg). The experimental setting demonstrated that the Valiant stent-graft remained apposed to the aortic wall at each increment of neck angulation and any degree of oversizing. Conversely, apposition of the proximal anchorage segment was neither seen with the Relay stent-graft beyond 80° landing zone angulation (1-7 mm) nor with the TAG stent-graft beyond 90° angulation (1-6 mm). The lack of device-to-wall apposition was greater with Relay stent-graft than with TAG stent graft (p = 0.009), while the “body” of both devices remained well apposed. Lack of “body” apposition (1.0-7.5 mm) was first observed with the Zenith stent-graft beyond 70° angulation (p < 0.001). An increase in stent-graft oversizing increased the lack of device-to-wall apposition for the TAG, Zenith and Relay stent-graft devices (p < 0.01). The better performance of the Valiant with respect to conformability versus the TAG or Relay stent-graft may be explained by the Valiant’s more robust radial force (13). In the aortic arch lack of attachment to the lesser curvature is usually caused by too little radial force. Malapposition in the arch may result in proximal type I endoleak or collapse of the endograft. The percentage of type I endoleak was reported from 0 to 44% (8, 14).

A proximal neck less than 2 cm from the left subclavian artery and the existence of an entry tear located at the lesser curvature of aortic arch may also predispose to endoleak. Usually type I endoleaks require additional stent-graft deployment for sealing, spot coiling or eventually conversion to surgery. In rare cases self resolution of type I endoleaks occurred between 1 week to 8 months (15); however, if the endoleak persists, progressive aneurysmal dilatation of the false lumen is likely, requiring ancillary procedures or conversion. Thus, initial coverage of the left subclavian or combined conventional transposition of the aortic arch branches may be necessary to improve proximal landing zone and avoid endoleak. Most left subclavian artery can be excluded safely and without complications. But, in order to be safe, both patency of the left carotid artery and the size of the vertebral artery with the connection to the Willis’ Circle needs to be examined before overstenting the left subclavian artery. In special cases when even the left common carotid artery originates from an aneurysm, a carotid-to-carotid bypass is required before placement of a stent-graft to exclude such aneurysms.

Appropriate sizing before stent-graft placement

Sealing, fixation and aortic wall apposition are often achieved through stent-graft oversizing. Choosing too small a stent-graft diameter can cause endoleak or migration, whereas excessive oversizing can lead to infolding of the graft or local trauma, including retrograde progression of the dissection (8). The method of measuring the appropriate size of the stent-graft in thoracic aortic disease seems to be a subject of ongoing debate in need of consensus, especially in aortic dissection; the diameter of a stent-graft can be determined in many ways ranging from the diameter of the proximal healthy aorta as a base-line to just visual estimates or 10-15% oversizing. There is, however, no data to confirm that a stent-graft is correctly sized when 10% larger than the average of the maximum and minimum diameters of the thoracic true lumen in acute dissection, or 20% in chronic dissection (16). The grafts are generally oversized by 3 to 4 mm in diameter to allow sufficient radial force for fixation. There is agreement that the ends of an endovascular graft device should be mildly oversized relative to the diameters of the proximal and distal landing zones, at least in the setting of true aneurysm. However, in dissection the issue is not settled yet and consensus has not been reached. The instructions for use of commercial devices usually recommend oversizing by around 10%; however, in recent reports of thoracic endograft series even oversizing of 20% to 30% was applied which may give better seal, but can set the stage for proximal device-induced dissection (17-19). With increased calcification of the aorta and different from a compliant vessel, oversizing will cause greater infolding of any stent-graft with low radial force. Undersizing is also associated with inadequate seal or loss of seal with neck expansion. Current recommendation for length of attachment zones afford a minimum of 15 mm, with length up to 30-40 mm in selected cases. Clinical experience with the Cook Zenith thoracic device has shown a higher incidence of complications when the attachment zone is shorter than 20 mm; similar observations have also been reported with other devices (20). The length of a
selected stent-graft should be determined according to measurement in the centerline of the aorta to avoid under-or overestimates from measurement in the lesser or greater curvature. When two stent-grafts are necessary in overlapped or “telescope” technique, the amount of overlap should probably be a minimum of 30 mm in straight anatomic segments, and up to 50 mm or more in angulated or curved segments of the aorta. Thoracic stent grafts are likely to induce considerable remodeling of the aorta after deployment for various reasons; remodeling is most evident in aortic dissection with opening the true lumen and regression of the false lumen. Stent-grafts are therefore exposed to the dynamics of continuous geometric alterations and changes in distraction forces, which may affect long-term durability of both the endograft and result of the repair. 

CHENG et al. used a computerized fluid dynamic technique to analyze the biomechanical factors associated with stent-graft remodeling in 12 patients over 12 months. The resultant drag force as a net change of fluid momentum was calculated on the basis of varying three-dimensional geometry and deployment position after performing computed tomography transaxial images (21). The drag force on the stent graft model increases in linear fashion with its internal diameter (10.3 N at a diameter of 26 mm and 26.8 N at a diameter of 42 mm) and becomes highest when the deployment position is closer to the proximal arch. The force is greatest at the top of the arch and decreases significantly when the proximal landing zone is in the descending aorta. An increase in mean inlet area ranged from 1030 ± 228 mm² to 1140 ± 279 mm², and in association with graft expansion the drag forces on the stent graft increased from 21.0 ± 3.5 N to 24.8 ± 3.4 N (21). On aggregate, endovascular stent-grafts placed closely to the aortic arch are subjected to significant displacement forces generated by high transversal blood flow and may result in distraction or migration of modular component grafts. Although device migration is a known complication of thoracic stent grafts, especially when used for aneurysm exclusion there is very little long-term data on thoracic endograft migration. The Gore TAG registry on thoracic aneurysms reported a total migration rate of 10% at 2 years (22). The Cook Zenith TX2 trial registered a device migration rate of 2.8% at 12 month (23). A study using the computer centerline of flow measurements in 194 patients recorded migration in 6.7% of thoracic devices (24) (Fig. 5).

**Stent-graft collapse**

Recent case reports have raised concerns of potentially devastating complications from total or near total endoprosthesis collapse or infolding especially with the TAG Gore system. This complication is not unique to a specific endograft, but has been observed with other brands including Talent and Zenith grafts. Most collapses have occurred in patients treated for aortic trauma or dissection and not in cases of atherosclerotic aortic aneurysms.
Different from aneurysm both trauma and dissection share anatomic factors predisposing for acute collapse with often location in smaller and younger aortas and extent into the aortic arch. Collapses were seen when stent-grafts were placed high in the aorta and presence of steeply angulated arches common in young patients. Such problem rarely occurs in longer and wider aortas associated with aeurysmal disease. A typical example is a 40-year-old man after aortic endoprothesis implantation with 18% oversizing for traumatic aortic rupture with sudden onset of hypertension and acute pulmonary edema six month after the procedure. Chest radiograph and thoracoabdominal computed tomographic angiography showed collapse of the endoprothesis with aortic obstruction and a type I endoleak, which was eventually treated with a second TAG graft (25). Iovi et al. reported the collapse of a Gore TAG endoprothesis in a patient with a traumatic isthmic rupture, which was treated by placement of an endoprothesis just distal to the origin of the LSA, with 37% oversizing of the diameter (26). Similar observations were described by Hinchliffe et al. in a series of seven patients with stent-graft collapse (27). However, it seems intuitive, that factors such as poor endograft to aortic wall appositioning due to an undersizing or less radial force, poor proximal landing zone (<2 cm) in an anulated aortic arch with resulting transversal distraction forces, endotension, which is defined by persistent or recurrent pressurization of an aneurysm sac after endovascular repair, without evidence of endoleak (28), low proximal flexibility, stiff stainless steel, covered proximal stents, and potentially other anatomic factors may all predispose to endoprothesis collapse.

Conclusion

The endovascular treatment of thoracic aortic pathologies is an established treatment option with excellent short-term results and several advantages over open surgery. For extended use of the technique, especially for aortic arch pathologies, current stent-grafts devices are limited by structural problems, lack of conformability, limited array of sizes and individual configurations to allow secure fixation. Disease-specific stent-grafts are probably needed for different pathologies, with devices for dissections being less traumatic and rigid and more flexible as current generation devices; moreover an individualized composition of grafted and non-grafted segments could be envisioned for dissection. For traumatic aortic lacerations (isthmic ruptures), smaller device diameters are necessary for normal-sized aortas with small access vessels. Device components including delivery system, graft material, and metal frame need further engineering work (29); the delivery system should be of low profile, highly flexible but maneuverable and rigid enough to resist kinking. The graft material should also be of low profile, strong and durable, and reasonably thin. The graft metal frame should provide high column strength, and resistance to compression and kink forces, as well as to corrosion and fatigue.

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